

Notice of Allowability

Application No.

10/607,909

Examiner

Traviss C. McIntosh

Applicant(s)

SOMMADOSSI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 4/3/06.
2. ☒ The allowed claim(s) is/are 1-7, 13-18, 37, 38, 43, 44 and 46-67.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 2/10/04 & 4/3/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHAOJIA ANNA JIANG, PH.D.
SUPERVISORY PATENT EXAMINER

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on April 3, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Moreover, as set forth in the Office Action mailed on 1/11/2006, page 3, wherein the examiner noted that further restriction may be required, a further restriction is set forth below.

Group I: Compounds and compositions wherein R is mono, di or triphosphate; a stabilized phosphate prodrug; acyl; sulfonate ester; or benzyl, wherein the phenyl group is optionally substituted; an amino acid; a carbohydrate; or other pharmaceutical acceptable leaving group which when administered *in vivo* provides a compound wherein R is independently H or phosphate.

Group II: Compounds and compositions wherein R is a lipid; a peptide; or cholesterol.

During a telephone conversation with Sherry Knowles on April 27, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7, 13-18, 37-38, 43-44, and 46-67. Affirmation of this election must be made by applicant in replying to this Office action.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

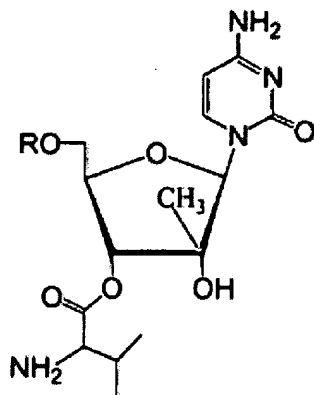
Authorization for this examiner's amendment was given in a telephone interview with Sherry Knowles on April 27, 2006.

The application has been amended as follows:

Claim 17 (currently amended): The compound of any of claims 1-3, wherein the compound is at least 90% by weight the β -D-isomer.

Claim 18 (currently amended): The compound of any of claims 1-3, wherein the compound is at least 95% by weight of the β -D-isomer.

Claim 37 (currently amended): A compound of the formula:



wherein R is mono, di or triphosphate; a stabilized phosphate prodrug; acyl; sulfonate ester; or benzyl, wherein the phenyl group is optionally substituted; an amino acid; a

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carbohydrate; or other pharmaceutical acceptable leaving group which when administered *in vivo* provides a compound wherein R is independently H or phosphate.

Claim 38 (currently amended): A pharmaceutical composition that comprises the compound of claim 1, 2, or 3 in a pharmaceutically acceptable carrier, wherein the 5'-hydroxyl group is replaced with a 5'-OR group, wherein R is mono, di or triphosphate; a stabilized phosphate prodrug; acyl; sulfonate ester; or benzyl, wherein the phenyl group is optionally substituted; an amino acid; a carbohydrate; or other pharmaceutical acceptable leaving group which when administered *in vivo* provides a compound wherein R is independently H or phosphate.

Claims 1-7, 13-18, 37-38, 43-44, and 46-67 are allowed.

The following is an examiner's statement of reasons for allowance: the prior art is not seen to teach or fairly suggest the claimed compound, specifically one which has a 2'-methyl group and a 3'-valine moiety. The prior art is not seen to teach or fairly suggest the claimed compounds, prodrugs, nor compositions comprising the same.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss McIntosh III
April 28, 2006

Shaojia A. Jiang
Supervisory Patent Examiner
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 5/1/06